COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 16/11/2000

C(2000) 3227

NOT FOR PUBLICATION

COMMISSION DECISION

of 16/11/2000

amending the marketing authorization for the
medicinal product
for human use

"PegIntron – peginterferon alfa-2b"

(new pack size)

ONLY THE FRENCH AND THE DUTCH TEXTS ARE AUTHENTIC

(Text with EEA relevance)

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98,[2]

Having regard to Commission Regulation (EC) No 542/95[3] of 10 March 1995 concerning the examination of variations to the terms of a marketing authorization falling within the scope of Council Regulation (EEC) No 2309/93, and in particular Article 5(2) thereof,

Having regard to the applications to amend the marketing authorization issued by Commission Decision on 25 may 2000 concerning the medicinal product **"PegIntron – peginterferon alfa-2b"** entered in the Community register of medicinal products under Nos EU/1/00/131/001-025, submitted on 17 July 2000 under Article 4(1) of the said Commission Regulation,

Having regard to the favourable opinions of the European Agency for the Evaluation of Medicinal Products, delivered on 10 august 2000, 11 August 2000 by the Committee for Proprietary Medicinal Products,

Whereas:
(1) medicinal product **"PegIntron – peginterferon alfa-2b"** meets the requirements of Council Directives 65/65/EEC,[4] 75/318/EEC[5] and 75/319/EEC,[6] as last amended by Directive 93/39/EEC;[7]

1 OJ No L 214, 24. 8. 1993, p. 1.
2 OJ No L 88, 24.3.1998, p. 7.
3 OJ L 55, 11.3.1995, p.15.
4 OJ 22, 9.2.1965, p. 369/65.
5 OJ L 147, 9.6.1975, p. 1.
6 OJ L 147, 9.6.1975, p. 13.
7 OJ L 214, 24.8.1993, p. 22.

(2) the measures provided for in this Decision fall within the notification procedure applicable to minor variations as defined in Article 3(1)(a) of Commission Regulation (EC) No 542/95,

(3) in accordance with Article 5(2) of Commission Regulation (EC) No 542/95, this Decision shall take effect retroactively on the 31st day following receipt by the European Agency for the Evaluation of Medicinal Products of the applications for variations relating to it.

(4) Decision C(2000)1407 of 25 May 2000 authorising the placing on the market of the medicinal product **"PegIntron – peginterferon alfa-2b"** should therefore be amended,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000)1407 is hereby amended as follows:

(a) - **Article 1 is completed by** :

EU/1/00/131/026 - PegIntron - 50 micrograms - Powder and solvent for solution for injection - Subcutaneous use - Powder: vial (glass),Solvent: ampoule (glass) - 12 vials + 12 ampoules + 12 injection sets

EU/1/00/131/027 -PegIntron - 80 micrograms - Powder and solvent for solution for injection - Subcutaneous use - Powder: vial (glass),Solvent: ampoule (glass) - 12 vials + 12 ampoules + 12 injection sets

EU/1/00/131/028 -PegIntron - 100 micrograms - Powder and solvent for solution for injection - Subcutaneous use - Powder: vial (glass),Solvent: ampoule (glass) - 12 vials + 12 ampoules + 12 injection sets

EU/1/00/131/029 -PegIntron - 120 micrograms - Powder and solvent for solution for injection - Subcutaneous use - Powder: vial (glass),Solvent: ampoule (glass) - 12 vials + 12 ampoules + 12 injection sets

EU/1/00/131/030 -PegIntron - 150 micrograms - Powder and solvent for solution for injection - Subcutaneous use - Powder: vial (glass),Solvent: ampoule (glass) - 12 vials + 12 ampoules + 12 injection sets

(b) - Annex I (summary of product characteristics) is replaced by Annex I to this Decision;

(c) - Annex III (labelling and package leaflet) is replaced by Annex II to this Decision.

Article 2

This Decision shall apply from 18 August 2000.

Article 3

This Decision is addressed to SP Europe,73, rue de Stalle , B-1180 Brussels , Belgium.
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Done at Brussels, 16/11/2000

For the Commission

Ekki LIIKANEN
Member of the Commission